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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,009	08/17/2001	Theresa H. Smith	US 1257/01 (VA)	2825

7590 10/06/2004

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/931,009	SMITH, THERESA H.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### *Status of the claims*

Claims 1-11 are pending.

Applicants' amendment filed 23 August 2004, which cancels claims 12-15 and amends claims 1 and 5-7 has been entered. Also, applicants' request (filed 23 August 2004) for extension of time of one month has been entered.

The following Office Action is applicable to the pending claims 1-9. Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Please note that the text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "synovial cell"; it is not apparent as to whether or not the recitation refers to non-exposed cell population or exposed cell population. Suggest addition of the article "the" or "said" before "synovial cells". The dependent claims are also rejected.

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***Claim Rejections - 35 USC §102***

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuber *et al.* (US Pat. No. 5478810).

Stuber et al. teach a peptide consisting of the SEQ ID NO:2 sequence (i.e., GPRP) of the instant application wherein the C-terminal proline (i.e., the 4<sup>th</sup> residue) is amidated, i.e., GPRP-NH<sub>2</sub> (see column 1, lines 57-59 and the patent SEQ ID NO:1), which anticipates the instant claim 7.

Stuber et al. teach a peptide comprising the instant SEQ ID NO:2 sequence (i.e., GPRP) (see the patent claim 6, and SEQ ID NO:16, i.e., GPRPPP-NH<sub>2</sub>), and teach a medicament (i.e., therapeutic composition) comprising the SEQ ID NO:16 (see abstract). The Stuber et al. teachings anticipate the instant claim 5.

In the patent claim 6, Stuber et al. disclose the peptide amide form of SEQ ID NO:16 which is a pharmaceutical acceptable salt in the solution (see column 1, lines 7-12), which anticipates the instant claim 6.

Note that the recitation “the analog being substantially ineffective at inducing expression or production of cell adhesion molecules” is an inherent property of the claimed peptide, and said “inducing expression ...” appears to refer to an intended use for the peptide and there is no patentable weight associated with the use of said peptide because structure and biological activity/property of the peptide will not be altered due to the above-indicated use of said peptide. Thus, the above Stuber et al. teachings or disclosure is applied to the instant claims 5-7.

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*The Applicants' response to the rejection under 35 USC 102*

The response filed 23 August 2004 urges that the amendment to claim 7 would put in the current application in a condition of allowance (pages 7-8). The applicants' argument is unpersuasive because the amendment only obviates the rejection under 112, the 2<sup>nd</sup> paragraph but not the rejection under 35 USC 102. The amidated (C-terminal proline) SEQ ID NO:2 peptide is anticipated by the Stuber's patent (see the above rejection).

The response also discusses the telephonic interview on 23 August 2004. It is of note that during interview, Examiner confirmed the rejection under 35 USC 112, the 2<sup>nd</sup> paragraph is correct and pointed it out that the said Stuber's SEQ ID NO:2 that has an amidated carboxyl group at C-terminal proline anticipates the instant claim 7. The interview summary does not indicate allowability of this application with respect to the claim.

***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuber *et al.* (US Pat. No. 5478810).

Stuber *et al.* teach a peptide consisting of the SEQ ID NO:2 sequence (i.e., GPRP) of the instant application wherein the C-terminal proline (i.e., the 4<sup>th</sup> residue) is amidated, i.e., GPRP-NH<sub>2</sub> (see column 1, lines 57-59 and the patent SEQ ID NO:1), which is applied to the instant claim 7.

Stuber *et al.* does not expressly teach preparation of a pharmaceutical composition comprising the SEQ ID NO:1 peptide wherein carboxyl group of C-terminal proline residue is amidated. Yet, Stuber *et al.* teach use of the amidated peptide comprising SEQ ID NO:1 as a medicament (see abstract), which is applied to the instant claims 8-9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the pharmaceutical composition comprising the amidated peptide having SEQ ID NO:1 sequence, because the amide forms of the Stuber's peptides (including SEQ ID NO:1) act as clot inhibitors (see column 1, lines 8-12 *wherein Stuber et al. summarize the patent invention*, and lines 47-61), and because the amidated peptide offers an advantage that the peptide prevents the association of soluble fibrin chains while does not inhibit thrombin enzymatic activity, wherein the peptide amidated is small, easily synthesized and more potent than non-amidated clot inhibitory peptide, as taught by Stuber *et al.* (see columns 1, 3 and 5-6, and abstract) . Thus, one skilled in the art would have readily developed the pharmaceutical composition comprising the small amidated peptide and successfully arrived at the current

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invention. Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

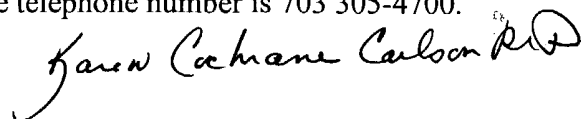
***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571 272-0949.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

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A handwritten signature in black ink, appearing to read 'SWL' followed by a long horizontal stroke.

Samuel Wei Liu, Ph.D.

September 7, 2004